

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

In re ALKERMES SECURITIES	)	Master Docket No. 03-CV-12091-RCL
LITIGATION	)	
	)	<u>CLASS ACTION</u>
_____	)	
This Document Relates To:	)	
	)	
ALL ACTIONS.	)	
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_____	)	

CONSOLIDATED COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES  
LAWS

## SUMMARY AND OVERVIEW

1. This is a securities class action on behalf of all purchasers of the common stock of Alkermes, Inc. (“Alkermes” or the “Company”) between April 22, 1999 and July 1, 2002 (the “Class Period”), against Alkermes and certain of its officers and directors for violations of the Securities Exchange Act of 1934 (the “Exchange Act”).

2. Alkermes is a biopharmaceutical company focused on the development of controlled-release drug delivery technologies and their application to existing or new drug therapies. Among the drug delivery technologies defendants seek to develop are sustained-release systems based on biodegradable polymeric microspheres, including those based on Medisorb polymers.

3. In 1996, Alkermes entered into an agreement with JPI Pharmaceutical International (“Janssen”), an affiliate of pharmaceutical giant Johnson & Johnson Pharmaceutical Research & Development, L.L.C. (“Johnson & Johnson”), to develop an injectable form of the schizophrenic drug Risperdal, based upon the Medisorb polymer technology, called Risperdal Consta. Janssen has marketed the oral form of Risperdal since 1993, with sales of \$2.3 billion in 2003. According to a December 12, 2001 report by analysts Thomas Weisel Partners, LLC (“Thomas Weisel”), during the Class Period, oral Risperdal was the most prescribed drug in the \$5.3 billion atypical antipsychotic market.

4. At the beginning of the Class Period, defendants signaled the achievement of an important milestone in the Medisorb-based technology. Defendants announced that, despite a variety of challenges, they had succeeded in the development and scale-up of current Good Manufacturing Practices (“cGMP”) production, using the Medisorb technology, of commercial scale production for Risperdal Consta.

5. During the Class Period, defendants further assured investors that the deal made with Risperdal Consta joint-venture partner Janssen would be profitable to the Company, particularly

since an agreement had been negotiated to secure, aside from the anticipated royalties and manufacturing payments under previous agreements, certain guaranteed financial payments and arrangements to eliminate significant financial risks.

6. During the Class Period, defendants artificially inflated the price of Alkermes shares by issuing a series of materially false and misleading statements about the Company's New Drug Application ("NDA") for Risperdal Consta.

7. On August 31, 2001, Alkermes submitted a NDA for Risperdal Consta. Defendants knew or were deliberately reckless in not knowing that despite their representations otherwise to the market, difficulties with pre-clinical studies requested by the Food and Drug Administration ("FDA") in 1998 and ongoing during the Class Period meant that the NDA for Risperdal Consta would not be approved by the FDA on July 1, 2002.

8. Also known to defendants throughout the Class Period was that the Wilmington, Ohio facility, repeatedly represented to the public as being capable of full-scale commercial production of Risperdal Consta, was unable to produce the Medisorb polymer at the scale required for commercial production. Rather, raw material difficulties, including variations in the molecular weight of Medisorb polymer, as well as manufacturing-process and equipment problems plagued the Risperdal Consta production, making commercial production at the necessary commercial scale impossible.

9. Defendants misrepresented the amount of revenue expected by Alkermes from sales of Risperdal Consta. Although during the Class Period, defendants told analysts to model around a 10% revenue stream, in fact, defendants failed to disclose that the revenue stream from Risperdal Consta was based upon a volume of sales formula stretching out to 2012. Defendants' statements to the market were made without any reasonable basis. As senior personnel acknowledged, due to

minimum payment clauses, Alkermes would likely have made more money by *not* producing Risperdal Consta rather than receiving reduced revenue from low sales volume.

10. As a result of defendants' false statements, Alkermes stock traded at inflated prices during the Class Period, increasing to as high as \$70.06 on February 16, 2000, allowing the Company to sell \$200 million of its own securities.<sup>1</sup>

11. On July 1, 2002, defendants announced the receipt of a non-approvable letter from the FDA for Risperdal Consta. As a result of this announcement, Alkermes' stock price dropped precipitously over the next two days to a low of \$4.04, or a loss of 93% from its Class Period high of \$98 per share, on total volume of 29 million shares.

### **JURISDICTION AND VENUE**

12. Jurisdiction is conferred by §27 of the Exchange Act. The claims asserted herein arise under §§10(b) and 20(a) of the Exchange Act and Securities and Exchange Commission ("SEC") Rule 10b-5, promulgated thereunder.

(a) Venue is proper in this District pursuant to §27 of the Exchange Act. Many of the false and misleading statements were made in or issued from this District.

(b) The Company's principal executive offices are in Cambridge, Massachusetts, where the day-to-day operations of the Company are directed and managed.

### **THE PARTIES**

13. Lead Plaintiff Southern Alaska Carpenters Retirement Trust purchased Alkermes common stock as described in the previously filed certification and was damaged thereby.

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<sup>1</sup> All share and per-share amounts have been adjusted for Alkermes' 2-for-1 stock split in May 2000.

14. Defendant Alkermes is a biopharmaceutical company focused on the discovery, development and commercialization of new small molecule drugs for the treatment of cardiovascular diseases. During the Class Period, defendants caused the Company to sell \$200 million of its securities.

15. Defendant Richard F. Pops (“Pops”) has been the Chairman and Chief Executive Officer (“CEO”) of Alkermes since February 1991. Pops currently serves on the Board of Directors of: (a) Alkermes; (b) Neurocrine Biosciences, Inc.; (c) Reliant Pharmaceuticals, LLC (“Reliant”); (d) CombinatoRx, Inc.; (e) the Biotechnology Industry Organization (BIO); (f) the Massachusetts Biotechnology Council (MBC); (g) the New England Healthcare Institute (NEHI); and (h) the Harvard Medical School Board of Fellows. He also serves as Chair for the Harvard Medical School Advisory Council for Biological Chemistry & Molecular Pharmacology (BCMP). In the years 1999, 2000, 2001 and 2002, Pops received salaries of \$354,904, \$395,192, \$406,462 and \$438,665, respectively; bonuses of \$150,000, \$175,000, \$175,000 and \$200,000, respectively; and other compensation, including loan forgiveness from the Company of \$5,374, \$274,800, \$275,100 and \$5,100, respectively. During the Class Period, Pops sold 663,312 of his Alkermes shares, for net proceeds of \$20.3 million.

16. Defendant Robert A. Breyer (“Breyer”) was President of Alkermes from July 1994 to December 2001 and Chief Operating Officer (“COO”) from July 1994 to February 2001. Breyer has been a director of Alkermes since July 1994. From August 1991 to December 1993, Breyer was President and General Manager of Eli Lilly Italy, a subsidiary of Eli Lilly and Company (“Eli Lilly”). From September 1987 to August 1991, he was Senior Vice President of Marketing and Sales of IVAC Corporation, a medical device company and a subsidiary of Eli Lilly. In the years 1999, 2000, 2001 and 2002, Breyer received salaries of \$257,942, \$285,000, \$294,685 and \$241,692,

respectively; bonuses of \$75,000, \$100,000, \$100,000 and \$200,000, respectively; and other compensation, including loan forgiveness from the Company of \$6,900, \$184,558, \$184,800 and \$4,269, respectively. During the Class Period, Breyer sold 522,375 of his Alkermes shares, for net proceeds of \$14.7 million.

17. Defendant David A. Broecker (“Broecker”) has been the COO of Alkermes since March 2001. In this role, he is responsible for managing all aspects of development, clinical, regulatory, manufacturing and quality for Alkermes’ partnered and proprietary products. Prior to joining Alkermes, Broecker worked over 13 years with Eli Lilly in a variety of positions, including manufacturing, sales, marketing and business development. In addition, he was the general manager of Eli Lilly’s operations in Germany and Ireland, where he led manufacturing operations for products accounting for 50% of worldwide Eli Lilly sales. He received his B.A. in chemistry from Wabash College, an M.S. in chemical engineering from the Massachusetts Institute of Technology and his M.B.A. from the University of Chicago. In the years 2001 and 2002, Broecker received a partial-year salary of \$24,327 and \$286,346, respectively; bonuses of \$194,791 and \$100,000, respectively; and other compensation, including loan forgiveness from the Company of \$126,174 in 2002.

18. Defendant Michael J. Landine (“Landine”) is Vice President of Corporate Development, having joined the Company in 1988 as Vice President and Chief Financial Officer (“CFO”), a position he held for 10 years. Previously, he was the CFO of The Walker Magnetics Group, Inc. (“Walker Magnetics”), an international manufacturer of industrial equipment. Landine currently serves on the Board of Directors of a private life sciences company, Expressive Constructs, Inc., and on the Board of Kopin Corporation, a manufacturer of high definition imaging products. He is also an advisor to the Board of Directors of Walker Magnetics. He received a B.S. in

Accounting from Bentley College and is a Certified Public Accountant. In the years 1999, 2000, 2001 and 2002, Landine received salaries of \$200,000, \$219,861, \$232,654 and \$244,564, respectively; bonuses of \$0, \$30,000, \$35,000 and \$55,000, respectively; and other compensation, including loan forgiveness from the Company of \$5,670, \$4,712, \$5,100 and \$5,100, respectively. During the Class Period, Landine sold 183,500 of his Alkermes shares, for net proceeds of \$5.4 million.

19. Defendant James M. Frates (“Frates”) has been Vice President, CFO and Treasurer of Alkermes since July 1998. Frates joined Alkermes with more than eight years of biotechnology investment banking experience. At Alkermes, Frates manages Finance, Intellectual Property, Investor Relations and Human Resources. Frates oversaw the pending acquisition of Reliant, as well as Alkermes’ \$200 million convertible bond issue. Previously, Frates was a Vice President in charge of the East Coast Life Sciences Practice at Robertson Stephens & Company where he was involved in over 30 transactions for clients, such as Genzyme, Gilead, Vertex and Alexion. Frates began his financial career in health care investment banking at Morgan Stanley & Company. He also spent a year teaching secondary school at the Royal Shrewsbury School in the U.K., as the Harvard College Fellow. He received a B.A. in Government from Harvard College and an M.B.A. from Harvard Graduate School of Business Administration. In the years 1999, 2000, 2001 and 2002, Frates received salaries of \$161,420, \$246,029, \$259,119 and \$275,948, respectively; bonuses of \$15,000, \$40,000, \$60,000 and \$75,000, respectively; and other compensation, including loan forgiveness from the Company of \$3,069, \$4,800, \$5,100 and \$5,100, respectively. During the Class Period, Frates sold 86,000 of his Alkermes shares, for net proceeds of \$2.8 million.

20. Defendant James L. Wright (“Wright”) was made Senior Vice President of Research and Development of Alkermes in December 2001 and has been a Senior Vice President of Advanced

Inhalation Research, Inc. since September 1999. From December 1994 to September 1999, Wright was Vice President of Pharmaceutical Development at Alkermes. From 1989 to 1994, he was employed at Boehringer Ingelheim Pharmaceuticals, Inc., most recently as a director. Wright received a B.A. in Chemistry and Biology from the University of California, Santa Barbara and a Ph.D. in Pharmacy from the University of Wisconsin. In the years 1999, 2000, 2001 and 2002, Wright received salaries of \$182,119, \$202,102, \$211,335 and \$237,766, respectively; bonuses of \$30,000, \$40,000, \$70,000 and \$75,000, respectively; and other compensation, including loan forgiveness from the Company of \$3,594, \$112,800, \$113,100 and \$5,100, respectively. During the Class Period, Wright sold 5,000 of his Alkermes shares, for net proceeds of \$164,000.

21. The individuals named as defendants in ¶¶15-20 are referred to herein as the “Individual Defendants.” A summary of the Individual Defendants’ compensation during the Class Period is as follows:

<i><b>Individual Defendant</b></i>	<i><b>Fiscal year</b></i>	<i><b>Salary (\$)</b></i>	<i><b>Bonus (\$)</b></i>	<i><b>Other Compensation (\$)</b></i>	<i><b>Total Compensation (\$)</b></i>	<i><b>Total Insider Sales</b></i>
<b>Pops</b>	2002	438,665	200,000	5,100	<b>643,765</b>	<b>\$20.3 million</b>
	2001	406,462	175,000	275,100	<b>856,562</b>	
	2000	395,192	175,000	274,800	<b>844,992</b>	
	1999	354,904	150,000	5,374	<b>510,278</b>	
<b>Breyer</b>	2002	241,692	200,000	4,269	<b>445,961</b>	<b>\$14.7 million</b>
	2001	294,685	100,000	184,800	<b>579,485</b>	
	2000	285,000	100,000	184,558	<b>569,558</b>	
	1999	257,942	75,000	6,900	<b>339,842</b>	
<b>Broecker</b>	2002	286,346	100,000	126,174	<b>512,520</b>	
	2001	24,327	194,791	0	<b>219,118</b>	



<i><b>Individual Defendant</b></i>	<i><b>Fiscal year</b></i>	<i><b>Salary (\$)</b></i>	<i><b>Bonus (\$)</b></i>	<i><b>Other Compensation (\$)</b></i>	<i><b>Total Compensation (\$)</b></i>	<i><b>Total Insider Sales</b></i>
<b>Landine</b>	2002	244,564	55,000	5,100	<b>304,664</b>	<b>\$5.4 million</b>
	2001	232,654	35,000	5,100	<b>272,754</b>	
	2000	219,861	30,000	4,712	<b>254,573</b>	
	1999	200,000	0	5,670	<b>205,670</b>	
<b>Frates</b>	2002	275,948	75,000	5,100	<b>356,048</b>	<b>\$2.8 million</b>
	2001	259,119	60,000	5,100	<b>324,219</b>	
	2000	246,029	40,000	4,800	<b>290,829</b>	
	1999	161,420	15,000	3,069	<b>179,489</b>	
<b>Wright</b>	2002	237,766	75,000	5,100	<b>317,866</b>	<b>\$164,000</b>
	2001	211,335	70,000	113,100	<b>394,435</b>	
	2000	202,102	40,000	112,800	<b>354,902</b>	
	1999	182,119	30,000	3,594	<b>215,713</b>	

22. The Individual Defendants, because of their positions with the Company, possessed the power and authority to control the contents of Alkermes' quarterly reports, press releases and presentations to securities analysts, money and portfolio managers and institutional investors, *i.e.*, the market. Each defendant was provided with copies of the Company's reports and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them but not to the public, each of these defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public and that the positive representations which were being made were then materially false and misleading. The Individual Defendants are liable for the false statements pleaded herein as those statements were each "group-published" information, and the result of the collective actions of the Individual Defendants.

### **CONTROL PERSONS**

23. The officer and/or director defendants identified above, because of their positions of control and authority as officers and/or directors of the Company, were able to and did control the contents of the various quarterly and annual financial reports, SEC filings, and press releases pertaining to Alkermes. In addition, as a result of their executive and managerial positions with Alkermes, each Individual Defendant had access to the adverse non-public information about Alkermes' business, finances, products, markets and present and future business prospects particularized herein, via access to internal corporate documents, conversations or connections with corporate officers and employees, attendance at Alkermes management and/or Board of Directors' meetings and committees thereof and via reports and other information provided to them in connection therewith.

24. The Individual Defendants are liable under §20(a) of the Exchange Act for the false statements and fraudulent schemes pled herein at ¶¶59-106, as those false statements and the fraudulent schemes were the result of the collective actions of the Individual Defendants, who were "control persons" of the Company. In addition to their roles as executives of the Company, the Individual Defendants were chief spokespersons for the Company. As such, the Individual Defendants are also liable for such statements under §10(b) of the Exchange Act and the "group published information" inference.

25. With regard to financial reporting, management is responsible for the preparation, presentation and integrity of Alkermes' financial reporting principles and internal controls and procedures designed to assure compliance with accounting and applicable laws and regulations.

### **BASES OF ALLEGATIONS**

26. Numerous former Alkermes employees have provided plaintiff with information demonstrating the problems occurring at the Company with the production of Risperdal Consta and

defendants' knowledge about these problems. The witnesses provided information to plaintiff on a confidential basis and are particularly described by job description, title, and/or duration of employment, thereby providing sufficient detail demonstrating that each was in a position to know the information s/he provided and thus the reliability of her/his accounts. The confidential witnesses come from different parts of the Company and accordingly provide different pieces of the fraud.

27. Confidential witness 1 ("CW1") was an Alkermes polymer production operator at both the Blue Ash and Wilmington facilities from January 2001 to June 2001. In that capacity, CW1 performed viscosity tests on the polymers produced in the new 10-gallon reactor in Wilmington. CW1 also performed tests on polymers in the Blue Ash facility.

28. Confidential witness 2 ("CW2") was a quality control chemist at Alkermes from the beginning of 2000 through August 2002, who worked at the Blue Ash facility and then the Wilmington facility. As a quality control chemist, CW2 performed routine quality testing on all stages of the Risperdal Consta product, including raw materials, in-process and finished product samples. CW2 confirmed the difficulties transferring the production of Risperdal Consta from one site to the other and that parts of the production continued at Blue Ash due to difficulties encountered in Wilmington.

29. Confidential witness 3 ("CW3") was a facilities manager at the Wilmington facility from the beginning of 2002 through September 2003. CW3 was responsible for the support equipment, such as air conditioning, of the production equipment at the Wilmington facility. In that position, CW3 observed problems with the manufacturing process, specifically recalling significant problems with the fills for Risperdal Consta. In addition, CW3 attended daily production and quality control meetings in which the fill difficulties were discussed. CW3 confirmed that as of September

2003, the new, larger commercial manufacturing area being built as an addition to the Wilmington facility was not completed.

30. Confidential witness 4 ("CW4") was a manager of the quality control laboratory at Alkermes from 1996 until April 2001 at both the Blue Ash and Wilmington facilities. In that capacity, CW4 oversaw stability testing for both the polymers manufactured in Ohio and the final Risperdal Consta product used for clinical studies and samples submitted to the FDA. CW4 confirmed the difficulties in the scale-up process preparing Risperdal Consta for commercial production in the Wilmington facility.

31. Confidential witness 5 ("CW5") was a director of analytical chemistry in Cambridge, Massachusetts prior to the Class Period. CW5 confirmed that problems occurred with Nutropin Depot such as the development of a mass under the skin at the point of injection, which outweighed the benefit of the drug. CW5 believed that the poor sales were the reason that Alkermes recently announced the discontinuation of Nutropin Depot.

32. Confidential witness 6 ("CW6") was a director of quality control at Alkermes in the Blue Ash and Wilmington facilities through September 2002. As a director of quality control, CW6 was responsible for the quality control for products manufactured in the Wilmington facility, including Risperdal Consta. CW6 worked closely with the FDA on behalf of Alkermes and worked closely with Alkermes' partner Janssen on efforts to prepare Risperdal Consta for commercial manufacturing. CW6 confirmed the difficulties encountered transferring the polymer production from Blue Ash to Wilmington for commercial production of Risperdal Consta and the fill problems that occurred at the Wilmington facility.

33. Confidential Witness 7 ("CW7") was an administrative assistant for the Medical Affairs Department at Alkermes from April 2001 through mid-2002 at the Cambridge,

Massachusetts headquarters. In that capacity, CW7 was responsible for providing administrative support to the Medical Affairs Department, which included the clinical operations group and the biostatistics/analysis group. CW7 explained that clinical operations was responsible for coordinating the clinical studies for Alkermes products (including Risperdal Consta and Nutropin Depot), putting together the FDA applications and presenting the clinical study information to the FDA.

### **FRAUDULENT SCHEME AND COURSE OF BUSINESS**

34. Through a series of false and misleading statements, defendants engaged in a fraudulent scheme and course of business that operated as a fraud or deceit on purchasers of Alkermes common stock that (a) deceived the investing public regarding Alkermes' prospects and business; (b) artificially inflated the prices of Alkermes' common stock; (c) allowed defendants to sell \$200 million of Alkermes securities at artificially inflated prices; (d) allowed Alkermes to enter into an agreement to complete its acquisition of Reliant using Alkermes shares at artificially inflated prices; (e) allowed several defendants to sell their own shares at artificially inflated prices for insider trading proceeds of over \$43 million; and (f) caused plaintiff and other members of the class to purchase Alkermes common stock at falsely inflated prices.

35. From the start of the Class Period, defendants represented to the market that they were prepared to manufacture and produce the schizophrenic drug Risperdal Consta at full commercial scale. Throughout the Class Period, while Alkermes and its partner Janssen completed clinical trials of Risperdal Consta and submitted an NDA to the FDA, Alkermes repeatedly emphasized to the market its ability to manufacture Risperdal Consta.

36. In fact, throughout the Class Period, as a result of a long series of significant production and design flaws, defendants were wholly unable to produce Risperdal Consta at commercial scale. According to CW6, in February 2000, defendants had discovered a problem with the polymer microspheres that encased the Risperdal drug. Due to not only raw material problems,

but also instability in the make-up of the compound itself, the molecular weight of the polymers varied from lot to lot. Rather than acknowledging these difficulties to the public, on May 19, 2000, defendants patented a method of preparing the microparticles that only masked and did not solve the quality issues, and allowed defendants to continue with their fraudulent scheme.

37. At the same time, Alkermes experienced difficulties in transferring the manufacturing of the polymers from the research facility at Blue Ash to the commercial scale production facility at Wilmington, Ohio. According to CW1, the planned transfer was still incomplete by December 2001, long after defendants represented that they had achieved full-scale commercial production capabilities. For example, according to CW2, as defendants tried to transfer the polymer production to the Wilmington facility, the machines responsible for filling the vials with the Risperdal Consta drug were not functioning properly, resulting in varying dosage weights. As a result, entire batches had to be discarded, and the Company ran fills 24-hours a day to try and manufacture some useful product. According to CW3, these facilities were still unprepared for full-scale commercial manufacturing by the end of the Class Period.

38. Defendants also misrepresented to the market the degree of royalties they were likely to receive for the production of Risperdal Consta. Throughout the Class Period, defendants told analysts to base their financial models on assumptions of a 10% return on investment. In fact, according to confidential witnesses, Alkermes was not to receive anything close to this number. Rather, the return on investment was based on a sales volume formula, stretching out to 2012. Risperdal Consta was unlikely to become profitable for defendants unless they achieved the high end of the sales projections, an unlikely scenario.

39. On August 31, 2001, defendants submitted their NDA for Risperdal Consta to the FDA. Betting heavily on the FDA's approval of Risperdal Consta, on March 21, 2002, defendants

entered into a stock-based merger with Reliant, a pharmaceutical company largely known for its marketing abilities. This stock-based transaction exchanged approximately \$934 million of Alkermes stock for complete ownership of Reliant. Although defendants expected to close this transaction based on the overly inflated value of the Company's stock, they could not control the timing of the FDA's issuance of a rejection letter for Risperdal Consta.

40. On July 1, 2002, at the close of the Class Period, the FDA issued a non-approvable letter for Risperdal Consta, based on toxicological studies on the drug, and problems that were known to defendants prior to and throughout the Class Period. As a result of the announcement, Alkermes' stock dropped over a two day period from a high of \$16.01 to a low of \$4.04, a drop of 74.8%.

## **SCIENTER**

### **A. Motive**

41. Defendants were motivated to perpetrate this fraud in order to ensure the approval of Risperdal Consta. Alkermes is a small pharmaceutical company that has operated at a deficit since inception. Alkermes is heavily reliant on its collaborators, such as Johnson & Johnson, to fund its drug pipeline and production facilities. During the Class Period, Alkermes marketed only one drug, Nutropin Depot. According to CW5, Nutropin Depot was launched in June 2000 and faced poor sales due to a flawed product design. In fact, Nutropin Depot was withdrawn from the market in June 2004 because of these design issues. Risperdal Consta was Alkermes' second drug to reach clinical trials on human subjects, and to be submitted to the FDA for approval. According to CW7, Alkermes felt a sense of urgency to file the NDA for Risperdal Consta in order to begin to realize a profit on the drug. The Company's well being and future drug collaborations were heavily dependent on the approval of the NDA and commercial production for Risperdal Consta.

42. Defendants were further motivated to commit fraud in order to obtain cash through the issuance of securities. As a company, Alkermes had operated at a net-operating loss since being founded in 1987. As of March 31, 2002, Alkermes' accumulated deficit was \$343.9 million. For the years 1999, 2000, 2001 and 2002, Alkermes had cash, cash equivalents and short-term investments of \$163,419, \$337,367, \$254,928 and \$152,347, respectively. Alkermes operated at approximately a \$30 million deficit each quarter. On February 16, 2000, Alkermes announced the private placement of \$200 million aggregate principal amount of its 3-3/4 % convertible subordinated notes due 2007. This transaction closed on February 18, 2000. The offering was made through initial purchasers to qualified institutional buyers, and raised desperately-needed cash for Alkermes. News of this badly-needed financing sent shares soaring nearly 90% in value in the days following the announcement.

43. Defendants were further motivated to inflate their stock price because of their own aspirations to be acquired by a larger pharmaceutical company. During the Class Period, Alkermes attempted to acquire a pharmaceutical marketing company, Reliant, through a stock-based merger agreement. On December 17, 2001, Alkermes invested \$100 million in Reliant. On March 21, 2002, Alkermes announced an equity exchange with Reliant, allowing Reliant owners to receive 31.07 million shares of Alkermes stock, valued at \$934 million dollars, based upon the March 20, 2002 closing market price for Alkermes of \$30.05 per share, in exchange for complete ownership of Reliant. Reliant was a company also operating at a net loss. According to CW6, defendants were motivated to pile risk upon risk in acquiring Reliant to make Alkermes itself a more attractive acquisition target for larger pharmaceutical companies. After the receipt of the non-approvable letter, the Reliant merger was terminated, and by March 31, 2003, Alkermes' \$100 million investment in Reliant had to be entirely written off.



44. Defendants were also motivated to hide the true facts about Risperdal Consta in order to preserve their salaries, bonuses and other compensation, and to allow them to sell over \$43 million of stock throughout the Class Period at inflated prices. A chart of Alkermes' stock price and defendants' insider sales is attached below. If the truth were known about Alkermes, defendants' compensation and the value of their stock would have been jeopardized.



## **B. Knowledge/Deliberate Recklessness**

45. In addition to the above-described involvement, each Individual Defendant had knowledge of Alkermes' problems and was motivated to conceal such problems. Landine and Frates, as CFOs, were responsible for financial reporting and communications with the market. Many of the internal reports showing Alkermes' forecasted and actual growth were prepared by the

finance department under Landine and Frates' direction. Defendant Pops, as CEO and Chairman, was responsible for press releases issued by the Company. Wright, as Vice President of Research and Development, was responsible for development and manufacturing readiness. Each Individual Defendant sought to demonstrate that he could lead the Company successfully and generate the growth expected by the market.

46. According to CW6, Individual Defendants Broecker and Breyer attended monthly project review meetings at the Company's headquarters in Cambridge, Massachusetts, along with senior management of Alkermes. At these monthly meetings, senior management discussed the progress of the Risperdal Consta production and NDA application for Risperdal Consta to the FDA.

47. According to CW3, daily production and quality control meetings were held every morning at the Wilmington facility to discuss the production of Risperdal Consta. For example, the problematic "fills" detailed in ¶¶92-93 were discussed at these meetings. These meetings were sometimes attended by Individual Defendant Broecker.

## **BACKGROUND AND OVERVIEW**

### **A. About the Company and the Drug**

48. Defendant Alkermes is a biopharmaceutical company focused on the development of controlled release drug delivery technologies and their application to existing or new drug therapies. The Company's NDA for Risperdal Consta for the treatment of schizophrenia was filed with the FDA on August 31, 2001 and not approved until over two years later, after the Class Period, on October 29, 2003. Risperdal (Risperidone) belongs to a class of compounds referred to as atypical antipsychotics, used in the treatment of schizophrenia.

49. The Risperdal Consta development effort is the result of a partnership between Medisorb Technologies International L.P. ("MTI") and Janssen. MTI entered into a development agreement with Janssen on or about December 23, 1993. Alkermes acquired the Risperdal Consta

development program through the acquisition of MTI by its Alkermes Controlled Therapeutics Inc. II (“ACT II”) subsidiary in 1996. The original development agreement was followed by two licensing agreements signed on or about February 21, 1996. The original development agreement was then amended on or about March 8, 1997 (“Second Amendment”). A definitive Manufacturing and Supply Agreement (“Mfg. Agreement”) for a depot formulation of Risperidone was established on or about August 6, 1997. Other amendments and agreements occurred between the parties during the Class Period.

50. Risperdal Consta is a white powder made from Risperidone and the 7525 DL JN1 poly-(d,l-lactide-co-glycolide) Medisorb polymer.<sup>2</sup> Risperdal Consta is made by a combination of patented and proprietary processes that dissolve the Medisorb polymer, mix into it the Risperidone drug, and finally precipitate the polymer in the form of “microspheres.” The microspheres are formed and processed in a sterile environment, whereby a known amount of powder is deposited in clean sterile vials. Critical to the process are methods to obtain the proper particle size of the microspheres and the uniform distribution of the drug in the polymer. Biweekly injection dosage forms currently available in the U.S. include 25 mg, 37.5 mg and 50 mg. The 25 mg dosage form appears to be equivalent to a 2 mg oral dose.

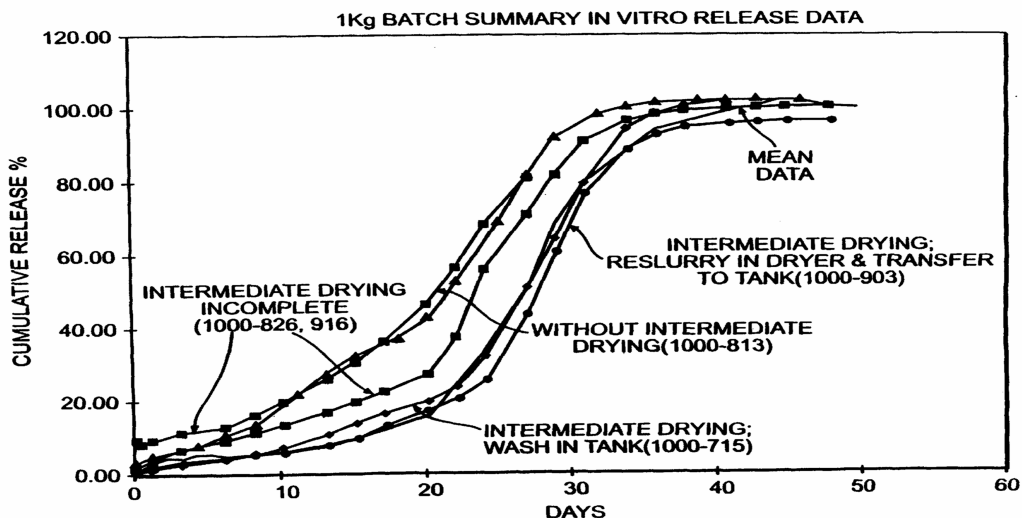
51. According to U.S. consumer information for the drug, Risperdal Consta is to be stored and used in the following manner: First, vials containing Risperdal Consta should be refrigerated at all times prior to use. To administer Risperdal Consta, the powder is diluted with an aqueous injection vehicle using a needle and syringe. The contents of the vial are shaken until a

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<sup>2</sup> The designation 7525 means that the polymer is composed of lactide (A) and glycolide (B) units in a 75/25 ratio, in a random (unknown) sequence of “A” and “B” units. Polymers composed exclusively of A or B units have much slower rates of hydrolysis than polymers composed of mixtures of A and B units.

suspension is formed, appearing thick and milky in color. The entire contents of the vial is withdrawn, an appropriate needle is employed, air bubbles removed and, by application of proper technique, the entire contents of the syringe is injected intramuscularly into the buttock of the patient.

52. The release of Risperdal from the Risperdal Consta drug product may be described by an “in vivo release profile,” the manner by which the drug entrapped in the Medisorb polymer matrix is released once the microspheres have been injected into the patient. For example, if the release profile demonstrates a “burst effect,” releasing too much of the drug into the patient within a 24-hour period, the patient might experience an extremely high dose of the drug, followed by a lower linear release over time. Alternatively, the release profile could be sigmoidal in nature, characterized by an initial lag in the release of the drug from the Medisorb polymer matrix, followed by a steep intermediate release phase, and ending in a flat final release phase. The defendants have a patented technology that they may employ to control the in vivo release profile, as illustrated by the following in vitro cumulative drug release plot of Risperidone from Medisorb polymer, as a percent of total drug released from the microparticles (microspheres), as determined at specific timepoints:



53. The 1997 Mfg. Agreement delineates the responsibilities of the parties in developing Risperdal Consta. Under the agreement, Alkermes is responsible for the commercial production of Risperidone, a “Manufacturing Readiness Plan,” by which Alkermes was required to commit such resources and undertake such maintenance and training programs as needed to keep ACT II manufacturing facilities in a state of readiness for commercial manufacture of Risperidone. The 1997 Mfg. Agreement also covers quality and regulatory considerations, including the preparation and filing of a facilities’ Drug Master File (“DMF”) with respect to the facilities where ACT II would manufacture the product and polymers.

54. A DMF is submitted to the FDA as a tool to protect confidential and detailed information about facilities, processes, or articles used in the manufacturing, processing, purchasing, and storing of drug products. DMFs allow a party other than the DMF holder to reference materials without disclosing to that party the contents of the file. The result is the maintenance of the confidentiality of the contents to the DMF holder. The FDA will typically not review the substantive elements of the DMF until it is ready to review the NDA or other application referencing the DMF.

55. Schizophrenia is a chronic, severe and disabling brain disease. Deterioration of brain matter can sometimes be detected or measured, and is particularly profound in children with early onset of the disease, affecting verbal memory, attention, reasoning, aggression and meaningful speech. According to the National Institute of Mental Health, approximately 1% of the world population suffers from schizophrenia in any given year. Thus, as many as 2 million people in the United States are affected. Schizophrenia can be difficult to diagnose, but is usually manifested in a variety of so-called positive and negative symptoms. Positive symptoms are usually manifested as hallucinations or delusions that distort a person’s sense of reality, often leading to paranoia. Negative symptoms are usually manifested as forms of isolation or withdrawal accompanied by poor

personal hygiene or general lack of motivation. Combinations of positive and negative symptoms are possible, resulting in a diagnosis of manic or bipolar disorders.

**B. Approvable and Discipline Review Letters**

56. Important to the investment community is the issuance of letters by the FDA in response to the filing of the NDA.

57. In a November 1997 letter to Congress regarding the reauthorization of the Prescription Drug User Fee Act (PDUFA) as part of the Food and Drug Administration Modernization Act of 1997, the Secretary of Health and Human Services committed the FDA to certain user fee performance goals and additional procedures related to the review of PDUFA products. These include the goals of reviewing and acting on increasing percentages of applicants' original NDA within six months for priority applications and within *10 months for standard applications for drugs and biologics*. The terms "review" and "act" mean the issuance of an action letter after the complete review of a filed application. In addition to the performance goals for application review, to help expedite the development of drugs and biologics, the Secretary specified that the FDA intends to provide early Agency thoughts on possible deficiencies to applicants in a letter as each discipline finishes its initial review of its portion of the pending application (except when it results in the ability to issue an action letter).

58. The development and approval process for a new drug has several phases:

(a) **Preclinical testing** – Before testing on human subjects, the FDA requires that a company conducts laboratory and animal studies to show biological activity of the compound against the targeted disease, and the compound is evaluated for safety.

(b) **Clinical Trials, Phase I** – The FDA then requires tests involving human subjects to study the drug's safety profile, including the safe dosage range. The studies also

determine how a drug is absorbed, distributed, metabolized, and excreted as well as the duration of its action.

(c) **Clinical Trials, Phase II** – In this phase, controlled trials of volunteer patients with the disease assess a drug's effectiveness.

(d) **Clinical Trials, Phase III** – This phase usually involves patients in clinics and hospitals, with physicians closely monitoring patients to confirm efficacy and to identify adverse events.

### **DEFENDANTS' FALSE AND MISLEADING STATEMENTS DURING THE CLASS PERIOD**

#### **False and/or Misleading Statement**

59. At the beginning of the Class Period, on April 22, 1999, defendants issued a press release entitled "Alkermes and Janssen Pharmaceutica to Proceed into Phase III Clinical Trials of Sustained Release Formulation of Anti-Psychotic Drug Risperdal®." The press release stated in part:

Alkermes, Inc. (NASDAQ: ALKS) announced today that Janssen Research Foundation, a division of Janssen Pharmaceutica, will proceed into Phase III clinical trials of an IM injectable sustained release formulation of the anti-psychotic drug RISPERDAL® (risperidone). The product candidate is based on Alkermes' Medisorb® drug delivery system and is designed to provide patients with prolonged therapeutic benefit from a single administration. The decision to proceed into Phase III clinical trials follows the successful completion by Janssen of Phase I and Phase II clinical trials of the product candidate *and the completion by Alkermes of scale-up and Phase III manufacturing activities at the expected commercial scale.*

"This is an important milestone in the development of this product candidate and of our Medisorb drug delivery technology," said Richard F. Pops, Chief Executive Officer of Alkermes. *"We have moved rapidly in the development and scale-up of this product candidate with our partners at Janssen Pharmaceutica. We look forward to the next phase of product development."*

**False and/or Misleading Statement**

60. Defendants confirmed that their facilities were ready for commercial scale production in the 10-K for the year ending March 31, 1999, filed with the SEC on June 29, 1999, which stated:

In April 1999, Janssen announced its intention to proceed with a Phase III clinical trial of RISPERDAL, after completing Phase I and Phase II clinical trials. ***In addition, we have completed scale-up and Phase III manufacturing activities at the expected commercial scale.*** We will manufacture the Medisorb formulation of RISPERDAL for both the clinical trials and commercial sales, if any.

61. The 10-K filed by Alkermes on June 29, 1999 was signed by defendant Pops on June 29, 1999 pursuant to the requirements of §13 or 15(d) of the Exchange Act. The Individual Defendants Pops, Frates and Breyer also signed the 10-K on June 29, 1999 pursuant to the requirements of the Exchange Act.

**Reasons Why False and/or Misleading**

62. The statements contained in the April 22, 1999 press release and June 29, 1999 10-K filing were false and misleading because defendants concealed the fact that the Medisorb manufacturing facilities were to be located at Wilmington, Ohio and were not ready for commercial scale manufacturing.

63. The Medisorb facilities were comprised of two parts: the research and development operations in the Blue Ash facility located at 6954 Cornell Road in Cincinnati, Ohio, and the manufacturing facility located approximately 35 miles north on Olinger Circle in Wilmington, Ohio. While defendant Pops announced the production of manufacturing lots at commercial scale, defendants concealed that they were still unable to produce the facilities' DMF for the Wilmington facility as required under the 1997 Mfg. Agreement, indicative of the fact that facilities, equipment and manufacturing process problems continued to exist at Wilmington. As of the April 22, 1999 press release, the only DMF in existence, established on March 15, 1990, was for the manufacture of Medisorb polymer at the Blue Ash facility in Cincinnati, Ohio. No such document had ever been



filed for the Wilmington facility for the production of Medisorb injectable sustained release drug delivery systems.

64. Defendants also concealed quality issues that plagued the production of the 7525 DL JN1 poly-(d,l-lactide-co-glycolide) Medisorb polymer used in the production of Risperdal Consta manufacturing lots. According to CW6, preparation of the Medisorb JN1 polymer was still best described as “art.” In fact, the JN1 polymer continued to be prepared in the Company's Blue Ash laboratories, a small experimental facility. Defendants knew that for a uniform process of manufacture of polymer, achieving control over important quality parameters such as consistent molecular weight was critical. Despite claims of readiness to manufacture at the expected commercial scale, unresolved issues in the polymer manufacturing process and its transfer to the Wilmington commercial manufacturing facility persisted.

65. In fact, CW1 stated that Alkermes was not ready to commercially manufacture Risperdal Consta prior to June 2001 and (possibly) had another two years until it would be ready. CW1 confirmed that Alkermes had problems in transferring the polymer production from the Blue Ash facility to the Wilmington facility. CW1 explained that the viscosity readings on the polymers produced in Wilmington were consistently too low such that the batches produced at the Wilmington facility could not be used for final production. According to CW1, the low viscosity was one of the main reasons for the delay in transferring the polymer production from Blue Ash to Wilmington. Given the difficulties, CW1 did not know when Alkermes expected the transfer to take place, but estimated that the transfer could not have been completed until at least December 2001.

**False and/or Misleading Statement**

66. The concern for the commercial production translated directly into Alkermes' bottom line. In fact, throughout the Class Period, defendants told analysts to run their financial models based upon an assumption of a 10% return on investment. For example, on December 21, 2000,

Needham & Co. (“Needham”) issued a report based on information provided by defendants that stated:

We recently spent time with Alkermes’ management and came away with increased confidence about the company’s outlook for 2001 and beyond.

A compelling feature of Alkermes is that it has developed true platform technologies that can be applied over and over again to generate a stream of new product candidates. *The technology is so valuable that it allows Alkermes to command roughly 10% of product sales in deals signed with corporate partners.*

\* \* \*

[I]n our view, a key aspect of Alkermes’ platform technology is that its contribution to a product candidate is extremely valuable to partners. Unlike other platform technologies that can contribute to the generation of new drugs, such as many of the genomics technologies like gene databases and target validation tools, *Alkermes’ contribution typically commands roughly 10% of product sales.* Most other platform technologies typically garner 1% or lower (or even no) royalties.

67. In an April 2, 2001 report, Needham stated:

For each drug commercialized by a partner using Alkermes’ technologies, *Alkermes receives revenues equivalent to roughly 10% of sales to take to its bottom line.* While we consider Nutropin Depot strong proof of concept, we expect Alkermes’s share of its second drug, Risperdal Depot [sic], could surpass \$40 million annually.

68. On September 4, 2001, Thomas Weisel issued an analyst report that stated:

We expect FDA approval and launch by 1QCY03 and estimate that peak sales of Risperdal LA could reach \$500mn. *Upon approval, Alkermes will manufacture Risperdal LA for commercial sale in exchange for manufacturing revenue and royalties on sales (that we estimate to be between 10%-12%).*<sup>3</sup>

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<sup>3</sup> As acknowledged by defendants after the Class Period, Alkermes specifically instructed analysts to base their financial models for Alkermes on a 10% assumption. In a conference call on February 11, 2004, defendant Frates stated, “On the Consta royalty, what we said is we get a majority of what -- *we have told you to model it around 10 percent*, so we get a majority that when we ship as a manufacturing fee, and a minority in terms of a royalty upon sale.”

**Reasons Why False and/or Misleading**

69. In fact, as acknowledged by CW6, defendants would not receive anything near a 10% royalty. Indeed, CW6 was present at a meeting of senior personnel where the royalty stream from Risperdal Consta was discussed. According to CW6, at that meeting, an Alkermes employee stated that it would be more profitable for Alkermes *not* to produce Risperdal Consta. This was because although there were minimum manufacturing payments due under the agreement, Alkermes did not stand to receive much profit unless a very high volume of the drug was sold. According to CW6, any revenue stream to Alkermes was based on a volume formula, stretching out until 2012. Risperdal Consta was unlikely to become profitable for Alkermes unless it achieved the high end of sales projections, an unlikely scenario.

**Insider Sales**

70. In January 2000, defendant Breyer sold 200,000 Alkermes shares, defendant Frates sold 8,000 Alkermes shares, defendant Landine sold 99,000 Alkermes shares and defendant Pops sold 350,000 Alkermes shares at prices between \$24.50 and \$25.50 per share.

**False and/or Misleading Statement**

71. On February 16, 2000, at a time when the Company's shares were already trading at artificially inflated prices, the Company issued a press release entitled "Alkermes Announces Placement of \$200 Million in Convertible Subordinated Notes." The press release stated in part:

Alkermes (NASDAQ: ALKS) today announced the private placement of \$200 million aggregate principal amount of its 3¾% Convertible Subordinated Notes due 2007. The offering, which was made through initial purchasers to qualified institutional buyers under Rule 144A under the Securities Act of 1933, is expected to close on February 18, 2000. Alkermes has also granted the initial purchasers of the notes an option to purchase up to an additional \$50 million in principal amount of the notes. The notes are convertible into common stock of Alkermes at a conversion price of \$135.50 per share, subject to adjustment in certain circumstances. Alkermes has agreed to file a registration statement for the resale of the notes and the common stock issuable upon conversion of the notes within 60 days after the closing of the offering.

**Reasons Why False and/or Misleading**

72. News of the success of this badly-needed financing reassured investors that the Company's products were viable and that the investment banking community stood behind the Company's science. As a company, Alkermes has operated at a net-operating loss since being founded in 1987. As of March 31, 2002, Alkermes' accumulated deficit was \$343.9 million. For the years 1999, 2000, 2001 and 2002, Alkermes had cash, cash equivalents and short-term investments of \$163,419, \$337,367, \$254,928 and \$152,347, respectively. According to CW6, Alkermes operated at approximately a \$30 million deficit each quarter. As a result of this financial announcement, defendants convinced investors that the Company's success was assured, as shares spiked nearly 90% in value in the days that followed the announcement.

**False and/or Misleading Statement**

73. On May 19, 2000, defendants caused Application Ser. No. 09,575,075 to be filed with the U.S. Patent and Trademark Office for the grant of a patent entitled "Method for Preparing Microparticles Having a Selected Polymer Molecular Weight." Among the details describing the preferred embodiments of the invention was the following statement explaining the key use of the method:

The methods of the present invention control the hold time and temperature of a polymer solution in order to control the molecular weight of the polymer in the finished microparticle product. In this manner, the methods of the present invention advantageously allow a selected polymer molecular weight to be achieved from a variety of starting material molecular weights. Alternatively, microparticle products of varying polymer molecular weights can be produced using the same molecular weight starting material. Thus, a range of products can be made from the same starting materials, thereby eliminating the need to reformulate the finished product to achieve the desired molecular weight of the polymer in the finished product.

**Reasons Why False and/or Misleading**

74. By seeking the approval of the patent application made on May 19, 2000, defendants sought to demonstrate expertise in the field and the capacity to create valuable intellectual property,

while concealing a desperate need to identify product manufacturing methods to “fix” the quality issues relating to wide variations in the quality of Medisorb polymer required for the manufacture of Risperdal Consta.

75. According to CW6, Alkermes was aware of the lot-to-lot variations in molecular weight of its polymer products long before the May 2000 patent application. Moreover, the Risperdal Consta finished product has a two-year shelf life. Substantial degradation of the polymer that occurs over time potentially renders the product ineffective. Thus, defendants patented an “erosion process” technology in an attempt to address this degradation, as well as to assure consistent molecular weight after the manufacturing process was complete. According to CW6, the patented process was an integral part of the Risperdal Consta technology because the molecular weight could otherwise not be controlled without the patented technology. Nowhere did defendants disclose that the patented process was necessary to “fix” quality issues in the production of the Medisorb polymers.

76. Defendants’ use of a manufacturing scheme that included either or both of patented methods, first to “erode” or “degrade” the Medisorb polymer in an organic solution of the polymer containing Risperdal, and secondly to control the “burst effect,” further complicated defendants’ efforts to achieve a cGMP compliant Risperdal Consta manufacturing process. The reason defendants sought new patented and proprietary processes that would actually complicate the Risperdal Consta manufacturing process was so that they could continue their concealment of quality issues relating to variation in the manufacturing process for the Medisorb polymer. Defendants sought these complications even though they realized that they would create significant obstacles in achieving a controlled manufacturing process capable of validation, a key requirement for FDA

inspection activities necessary to demonstrate readiness for manufacture of the product in the Wilmington facility.

### **False and/or Misleading Statement**

77. Defendants further misrepresented the commercial capabilities in their 10-K for the fiscal year ending March 31, 2000, filed with the SEC on June 29, 2000:

RISPERDAL. We are developing and manufacturing a Medisorb sustained release formulation of Janssen's anti-psychotic drug RISPERDAL. Janssen is an affiliate of Johnson & Johnson. In April 1999, Janssen announced its intention to proceed with two Phase III clinical trials of RISPERDAL Depot, after completing Phase I and Phase II clinical trials. ***In addition, we have completed scale-up and Phase III manufacturing activities at the expected commercial scale.*** We will manufacture the Medisorb formulation of RISPERDAL for both the clinical trials and commercial sales, if any. Janssen is responsible for conducting all clinical trials.

\* \* \*

We own and occupy approximately 35,000 square feet of manufacturing, office and laboratory space in Wilmington, Ohio. The facility contains a state-of-the-art GMP sterile production facility specifically designed for the production of Medisorb microspheres. Construction of a 20,000 square foot addition and renovation of this facility to support commercial scale manufacture of Medisorb product candidates was completed in June of 1998. ***We believe that our Wilmington facility is adequate for its preclinical, clinical and commercial operations.***

78. The 10-K filed by Alkermes on June 29, 2000 was signed by defendant Pops on June 29, 2000 pursuant to the requirements of §13 or 15(d) of the Exchange Act. Individual Defendants Pops, Frates and Breyer also signed the 10-K on June 29, 2000 pursuant to the requirements of the Exchange Act.

### **Reasons Why False and/or Misleading**

79. As referenced in ¶¶62-65, these statements were false and misleading. Furthermore, as revealed by CW6, these statements were false and misleading because, by at least February 2000 and continuing into 2001, defendants were experiencing severe problems producing Medisorb polymers. Beginning in February 2000, defendants discovered that Risperidone was being released

from the Risperdal Consta polymer into the bloodstream much more quickly than expected. By the end of 2000, Alkermes determined that a raw material – benzyl alcohol – was responsible for the spike in releasing the drug. Amongst the actual root causes for the problem, Alkermes documented that the benzyl alcohol used was outdated, had oxidized in storage and produced peroxide, a chemical that would degrade the polymer microspheres, resulting in faster release of the drug. The problem regarding the degradation of the microspheres was never completely solved, however, because there were also concerns about whether the degradation of the microspheres had an impact on the efficacy of Risperdal Consta. Meetings, attended by defendant Broecker, continued on into the summer of 2001 with the full effects of microsphere degradation on the efficacy of the drug still undetermined.

80. According to CW6, the Company took nearly two years to investigate why the unexpected and alarming early release of the drug into the bloodstream had occurred. The investigation also caused a temporary halt to efforts in the transfer of polymer production to the Wilmington manufacturing facility. Although there were concerns whether the degradation of the microspheres had an impact on the efficacy of Risperdal Consta, the lengthy investigation focused on the benzyl alcohol raw material and not the degradation of the microspheres.

### **Insider Sales**

81. In July 2000, defendant Breyer sold 75,000 Alkermes shares, defendant Frates sold 30,000 Alkermes shares, defendant Landine sold 40,000 Alkermes shares and defendant Pops sold 175,000 Alkermes shares at prices between \$44.09 and \$45.61 per share.

### **False and/or Misleading Statement**

82. On February 20, 2001, Alkermes issued a press release entitled “Alkermes Announces Milestones In Development Of Injectable Sustained Release Risperdal®,” which stated in part:

Alkermes, Inc. (NASDAQ: ALKS) today announced that its partner, Janssen Pharmaceutica, has completed two multi-center Phase III clinical trials of an IM injectable sustained release formulation of the anti-psychotic drug RISPERDAL® (risperidone). The formulation is based on Alkermes' Medisorb® injectable sustained release drug delivery system and is designed to provide patients with prolonged therapeutic benefit from a single administration. ***With the completion of the Phase III clinical trials, Alkermes and Janssen are preparing for the expected submission of a New Drug Application (NDA) to regulatory health authorities including the United States Food and Drug Administration (FDA).***

“We are pleased to be moving forward towards the commercialization of our injectable sustained release formulation of RISPERDAL,” said Richard Pops, Chief Executive Officer of Alkermes, Inc. “Our Medisorb injectable sustained release drug delivery system is designed to provide important dosing advantages to patients, their families and caregivers.”

### **Reasons Why False and/or Misleading**

83. The statements regarding the submission of the NDA were false and misleading when made, because, according to CW4, the Risperdal Consta drug application had already been delayed far beyond defendants' original timeline, due to a request from the FDA for additional pre-clinical studies of the product. Typically, pre-clinical studies are conducted on non-human subjects before a product is studied on humans in the phase studies. According to CW4, pre-clinical studies were conducted for Risperdal – the oral formulation of Risperdal Consta – by Janssen prior to its approval by the FDA. According to CW4, the FDA, however, requested additional pre-clinical studies in 1998 to demonstrate the long-term toxicological effects of Risperdal Consta in rats. The request from the FDA was specific to the injectable formulation of Risperdal Consta because the FDA wanted to know the long-term effects of injecting polymers into the body and whether there were any effects of residual polymer substance in the body. The additional pre-clinical studies lasted two and one-half years, and were conducted concurrently with the phase studies on humans. The non-approvable letter received from the FDA in July 2002 related to these unrevealed pre-clinical studies.



**Insider Sales**

84. From January 2001 through July 2001, defendant Breyer sold 135,000 Alkermes shares, defendant Frates sold 20,000 Alkermes shares, defendant Landine sold 18,000 Alkermes shares, defendant Pops sold 55,000 Alkermes shares and defendant Wright sold 5,000 Alkermes shares at prices between \$22 and \$34.65 per share.

**False and/or Misleading Statement**

85. Defendants again confirmed the capabilities of their commercial facilities in their 10-K for the year ending March 31, 2001, filed with the SEC on June 29, 2001:

RISPERDAL. We are developing and manufacturing a Medisorb sustained-release formulation of Janssen's anti-psychotic drug RISPERDAL. Janssen is an affiliate of Johnson & Johnson. In February 2001, Janssen notified us of the positive results of two multi-center Phase III clinical trials of an intra-muscular ("IM") injectable sustained-release formulation of RISPERDAL. With the completion of the Phase III clinical trials, we and Janssen are preparing for the expected submissions to regulatory agencies, including the FDA. *We will manufacture the Medisorb formulation of RISPERDAL for any future clinical trials and commercial sales, if any. Janssen will continue to provide funding to us as we continue the development of Medisorb RISPERDAL and as we prepare to be the commercial manufacturer.*

\* \* \*

We own and occupy approximately 50,000 square feet of manufacturing, office and laboratory space in Wilmington, Ohio. The facility contains a GMP production facility designed for the production of Medisorb microspheres on a commercial scale. *During 2000, we completed an expansion of our Medisorb commercial manufacturing facility in Wilmington, Ohio, to prepare for commercial scale manufacture of Medisorb RISPERDAL.* Additionally, we are currently planning to construct a second facility in Wilmington, Ohio for commercial manufacturing. We also lease and occupy approximately 30,000 square feet of laboratory and office space in Blue Ash, Ohio under a lease expiring in 2003.

86. The 10-K filed by Alkermes on June 29, 2001 was signed by defendant Pops on June 29, 2001 pursuant to the requirements of §13 or 15(d) of the Exchange Act. Individual Defendants Pops, Frates and Breyer also signed the 10-K on June 29, 2001 pursuant to the requirements of the Exchange Act.

### **Reasons Why False and/or Misleading**

87. The statements regarding the ability of Alkermes to produce Risperdal Consta at full-scale production were false and misleading when made because, as described in ¶¶62-65 and 79-80, and according to CW4, the Wilmington, Ohio plant was not ready for full-scale production in April of 2001. Not only was the Wilmington facility experiencing delay in ramping up manufacturing for commercial production of Risperdal Consta, but there were also difficulties in transferring the polymer production process from Blue Ash to Wilmington. The transfer of polymer production went so poorly that, in fact, through April 2001, polymer production remained in the Blue Ash facility. These production problems were independently confirmed by CW6 and CW3.

### **Insider Sales**

88. Between August 1, 2001 and August 17, 2001, defendant Landine sold 4,000 Alkermes shares, defendant Frates sold 4,000 Alkermes shares, defendant Pops sold 12,500 Alkermes shares and defendant Breyer sold 12,000 Alkermes shares at prices between \$26.46 and \$27.92 per share.

### **False and/or Misleading Statement**

89. On September 4, 2001, the Company issued a press release entitled “New Drug Application for First Injectable, Long-Acting Atypical Antipsychotic Submitted to FDA.” The press release stated in part:

A new drug application for a long-acting injectable formulation of Risperdal® (risperidone)\* has been filed with the Food and Drug Administration by Janssen Pharmaceutica Products, LP, and similar filings are now being submitted with health authorities worldwide. If approved, it would be the first atypical antipsychotic medication available in a formulation suitable for long-term use that requires administration just once every two weeks, instead of daily doses.

Using proprietary Medisorb® technology developed by Alkermes, Inc., the new formulation encapsulates risperidone in “microspheres” made of a biodegradable polymer, which is injected into the muscle. Laboratory and clinical research has shown that the microspheres gradually degrade at a set rate designed to

provide consistent levels of the drug in the bloodstream. The polymer from which the microspheres are made breaks down into two naturally occurring compounds that are then eliminated by the body. *Alkermes is scheduled to manufacture this long-acting formulation of Risperdal pending regulatory approval.*

#### **Reasons Why False and/or Misleading**

90. The statements made regarding the submission of the NDA to the FDA were false and misleading when made, because, as described in ¶83, and according to CW4, Alkermes had already experienced long delays in the filing of their application because of the FDA's requests for additional pre-clinical studies. These studies were focused on the long-term effects of residual polymer substance in the body and were related to the non-approvable letter eventually received for Risperdal Consta in July 2002.

91. In telling investors in the September 4, 2001 press release that the Company stood ready to manufacture Risperdal Consta, defendants misled the market into believing that the Wilmington facility was able to begin commercial manufacture of the product at the expected levels when they knew it was not.

92. Indeed, according to CW2, at the end of 2001, as defendants tried to move Risperdal Consta production from the Blue Ash facility to the Wilmington facility, "fill" problems developed. Near the final stage of production, there is a "fill team" responsible for operating machinery that measures out the dosages and "fills" and caps the vials that contain the finished product. When Alkermes transferred production to Wilmington, the fill machinery was not functioning properly, resulting in varying dosage weights. As a result, entire batches of the product could not be used and had to be discarded. The Company was running fills 24-hours each day in order to try and manufacture some useful product. Fill teams worked 16 hours at times, and the Company began running fills constantly by adding a second shift. Alkermes also began renting hotel rooms for the

fill team. According to CW6, because of the difficulties at the Wilmington facility, Alkermes continued production at the Blue Ash facility and extended the lease on the building.

93. In fact, as confirmed independently by CW3, consistent problems with the vial fills of Risperdal Consta continued throughout the Class Period. Fill problems were so bad that 50% of the batches produced in Wilmington had to be discarded. CW3 learned of these problems from being in close proximity to the clean rooms while working on the maintenance of the support equipment and from attending daily production team meetings at 8 a.m. CW3 also attended daily quality control meetings at 9 a.m., in which the problems with the fills were also discussed. Due, in part, to these fill problems, Alkermes extended its lease at the Blue Ash facility and was still occupying this research facility in September 2003.

#### **Insider Sales**

94. Between September 4 and October 25, 2001, defendant Pops sold 20,312 shares, defendant Landine sold 6,500 shares, defendant Frates sold 8,000 shares, and defendant Breyer sold 19,500 shares at prices between \$20.01 and \$26.05.

#### **False and/or Misleading Statement**

95. On October 30, 2001, the Company issued a press release entitled “Alkermes to Expand Production Facility to Meet Projected Demand for Long-Acting Formulation of Risperdal®.” The press release stated in part:

Alkermes, Inc. (NASDAQ: ALKS) today announced the signing of an agreement with Janssen Pharmaceutica that provides for the expansion of Alkermes’ manufacturing capacity for production of the new, long-acting injectable formulation of Risperdal® (risperidone). A new drug application (NDA) for the new formulation of Risperdal, currently the most widely prescribed antipsychotic medication in the United States, was submitted to the U.S. Food and Drug Administration on August 31, 2001. Risperdal is expected to be the first “atypical” antipsychotic to be available in a formulation that only requires administration every two weeks.

***“Our current manufacturing facility is fully equipped to support launch quantities and to meet the early demand projected for long-acting Risperdal,”***

stated David Broecker, Chief Operating Officer of Alkermes. “This expansion will include the construction of a separate, large-scale GMP facility on the same site and is designed to enable Alkermes to significantly expand our production capacity. Our agreement with Janssen eliminates the financial risk associated with the acceleration of this expansion.”

Pursuant to the agreement announced today, Alkermes has committed to expand its production capacity prior to FDA approval of the new Risperdal formulation in exchange for certain guaranteed financial payments. In addition, Alkermes will receive, under earlier agreements, royalties and manufacturing payments from Janssen upon successful commercialization of the new, long-acting Risperdal.

### **Reasons Why False and/or Misleading**

96. Nearly three months had elapsed between the signing of the Wilmington facility agreement and defendants’ announcement in the October 30, 2001 press release. Despite the claims in the press release regarding the ability of the Wilmington manufacturing facility to produce launch quantities and meet the early demand projected for Risperdal Consta once the FDA approved the NDA, defendants again concealed that they were still unable to produce the facilities’ DMF for the Wilmington facility as required under the 1997 Mfg. Agreement, indicative of the fact that facilities, equipment and manufacturing process issues continued to exist at the Wilmington facility. For example, according to CW6, problems in the transfer JN1 polymer production critical to support commercial-scale production of Risperdal Consta were not resolved until at least February of 2002. Thus, despite assertions to the contrary in the October 30, 2001 press release, defendants remained wholly unable to begin commercial manufacture of the product at the expected levels.

97. Another confidential witness, CW3, confirmed that at least up until September 2003, the commercial manufacturing space was still being built onto the Wilmington facility. In fact, in September 2003, the new area did not yet have plumbing or electrical wiring and the production machines had not yet been installed. Moreover, CW3 stated that although the Blue Ash facility was

supposed to close, Alkermes extended the lease and was still occupying the facility in September 2003.

**False and/or Misleading Statement**

98. On December 18, 2001, defendants issued a press release entitled “Alkermes and Reliant Pharmaceuticals Form Strategic Alliance.” Defendants announced in this press release that they had made a \$100 million equity investment in Reliant in exchange for approximately 19% ownership of the company:

Alkermes, Inc. (NASDAQ: ALKS) today announced a strategic alliance with Reliant Pharmaceuticals, LLC, a rapidly growing, privately held pharmaceutical company marketing branded, patent-protected pharmaceutical products to U.S.-based primary care and targeted specialty physicians.

The alliance provides Alkermes with a strategic partner for the acquisition, development, marketing and sales of proprietary pharmaceutical products. Pursuant to the agreements announced today, Alkermes has made a \$100 million equity investment in Reliant in exchange for approximately 19% ownership of the company. Alkermes’ investment was accompanied by a \$50 million investment by Pritzker family business interests and Bay City Capital, the major equity owners of Reliant.

In addition to the equity investment, the companies have agreed to explore collaborations in several areas, including the marketing or co-marketing by Reliant of Alkermes’ products, the co-development of new product candidates, the potential acquisition of products or product candidates from third parties, and the application of Alkermes’ proprietary drug delivery technologies and manufacturing capabilities to Reliant’s expanding product portfolio.

“This alliance accelerates our ability to develop, acquire and commercialize proprietary product candidates, particularly those that will be prescribed in the primary care physician’s office,” said Richard Pops, Chief Executive Officer of Alkermes. “Reliant has built a sophisticated commercialization infrastructure and an experienced Board and management team with an outstanding track record of success in the pharmaceutical industry. We look forward to expanding our relationship as we identify opportunities for collaboration.”

**False and/or Misleading Statement**

99. On March 21, 2002, the Company issued a press release entitled “Alkermes and Reliant Pharmaceuticals Announce Merger.” The press release stated in part:

Alkermes, Inc. (Nasdaq: ALKS) and Reliant Pharmaceuticals, LLC (“Reliant”) today announced that the Board of Directors of Alkermes and the Board of Managers of Reliant have each unanimously approved a definitive merger agreement between the two companies. The merger unites Reliant’s three marketed product brands, product development pipeline, extensive U.S. sales and marketing infrastructure and management team with Alkermes’ advanced drug formulation and development capabilities, pipeline of proprietary and partnered products and manufacturing capabilities to create a rapidly growing integrated pharmaceutical company.

The transaction is structured as a tax-free exchange of equity, in which non-Alkermes equity holders of Reliant will receive a total of 31.07 million shares of Alkermes stock or approximately 31% of the outstanding shares of the new company post-closing. Based upon the March 20, 2002 closing market price for Alkermes of \$30.05 per share, the purchase price for the portion of Reliant not already owned by Alkermes is \$934 million.

\* \* \*

“This merger is a major step in the execution of our strategy to become an integrated pharmaceutical company,” said Richard Pops, Alkermes CEO. “By adding Reliant’s highly experienced management team, its proven sales and marketing infrastructure and exciting drug development pipeline, Alkermes continues its evolution from a leading drug delivery company to a fast growing, integrated pharmaceutical company well positioned to bring important therapeutic products to patients and physicians.”

### **Insider Sales**

100. Between November 1, 2001 and February 26, 2002, defendant Landine sold 16,000 Alkermes shares, defendant Frates sold 16,000 Alkermes shares, defendant Breyer sold 54,000 Alkermes shares and defendant Pops sold 50,000 Alkermes shares at prices between \$24.23 and \$28.27 per share.

### **DEFENDANTS’ SCHEME BEGINS TO UNRAVEL**

#### **False and/or Misleading Statement**

101. On July 1, 2002, the Company issued a press release entitled “Alkermes Announces Receipt by Johnson & Johnson Pharmaceutical Research & Development of Non-Approvable Letter for Risperdal Consta<sup>TM</sup>.” The press release stated in part:



Alkermes, Inc. (Nasdaq: ALKS) today announced that Johnson & Johnson Pharmaceutical Research & Development, LLC has received a non-approvable letter from the U.S. Food and Drug Administration (FDA) related to its New Drug Application (NDA) for Risperdal Consta™ (risperidone) long-acting injection.

“One of the strengths of our business model is the quality of the pharmaceutical companies with whom we collaborate,” said Richard Pops, Chief Executive Officer of Alkermes. “Johnson & Johnson is one of the world’s leading health care companies. We have great confidence in relying on their ability and judgment in dealing with regulatory authorities around the world.”

Risperdal Consta is a long-acting injectable formulation of Risperdal® that uses Alkermes’ Medisorb® drug-delivery technology. If approved, Risperdal Consta will be manufactured by Alkermes and the product will be marketed by Janssen Pharmaceutica Products, L.P. in the United States, Janssen-Ortho in Canada and Janssen-Cilag elsewhere.

“Alkermes’ business is based on multiple drug delivery technologies and multiple product candidates with independent opportunities for commercial success,” said Richard Pops. “We are very committed to the success of Risperdal Consta. The ultimate success of our business, however, is not dependent solely upon it. We have a unique combination of personnel, technologies, financial resources and an operating plan that enables us to develop a broad pipeline of product candidates.”

#### **False and/or Misleading Statement**

102. Similarly, on July 1, 2002, Alkermes’ joint-venture partner, Johnson & Johnson, issued a press release entitled “Johnson & Johnson Pharmaceutical Research & Development Receives Non-Approvable Letter for Risperdal Consta.” The press release said in part:

Johnson & Johnson Pharmaceutical Research & Development, LLC (J&JPRD) today announced that it has received a non-approvable letter from the U.S. Food and Drug Administration (FDA) related to its New Drug Application (NDA) for Risperdal Consta(TM) (risperidone) long-acting injection. Issued at the 10-month goal FDA has set for responding to standard NDAs, the letter invited further dialogue with the agency to resolve questions regarding certain aspects of the pre-clinical data. No significant concerns were raised regarding the manufacturing process.

“We believe we will be able to satisfactorily resolve the FDA’s questions about the pre-clinical data,” said Harlan Weisman, MD, executive vice president of research and development at J&JPRD. “We look forward to doing so in an expeditious manner and moving ahead with the approval process.”

Risperdal Consta is a long-acting injectable formulation of Risperdal that uses Alkermes’ proprietary, injectable, extended-release, drug-delivery technology,



Medisorb®. The technology is based on the encapsulation of drugs into small polymeric microspheres that degrade slowly and release the medication at a controlled rate following subcutaneous or intramuscular injection. If it is approved, Risperdal Consta will be manufactured by Alkermes and marketed in the United States by Janssen Pharmaceutica Products, L.P.

“We believe Risperdal Consta will represent an important new treatment option for persons with schizophrenia by offering all of the benefits of an atypical antipsychotic in a long-acting form,” Dr. Weisman continued. “It has been estimated that as few as 25 percent of persons with schizophrenia take their medication on a consistent basis – a problem that can lead to relapse and re-hospitalization. Because of its two-week duration of effect, thus eliminating the need for daily pills, Risperdal Consta may help increase adherence to treatment.”

### **Reasons Why False and/or Misleading**

103. According to CW6, the issues raised in the July 1, 2002 non-approvable letter were related to the toxicological studies of Risperdal Consta. The toxicological section of the NDA contains pre-clinical information (or results of animal testing) addressing the safety of the risperidone drug substance. Some of the issues raised by the FDA about the pre-clinical data were previously raised when Janssen was seeking approval of the oral form of risperidone, Risperdal tablets. According to CW6, Alkermes should have expected this reaction and the issues raised by the FDA, because the same issues were encountered for Risperdal, the oral form of risperidone. In fact, the FDA reviewer of this section was the same individual that reviewed the toxicological section of the application for the Risperdal oral dosage form approximately 10-12 years prior.

104. According to CW4, another issue also raised in the FDA’s non-approvable letter was the results of the additional pre-clinical studies on the Medisorb polymer requested in 1998. The 1998 additional studies concerned the long-term effects of injecting polymers into the body. Specifically, CW4 said that the drug is encapsulated in a biodegradable polymer, and once the polymer is injected into the body, the body naturally erodes the polymer and the drug is released into the bloodstream. However, it takes some time for the body to completely erode the polymer, and in

1998, the FDA sought studies on the effects of having residual polymer substance in the body. According to CW4, the July 1, 2002 approvable letter was related, in part, to these studies.

105. Defendants omitted from their July 2002 press release that they were still unable to begin commercial manufacture of the product for the U.S. markets at the expected levels. In fact, in July 2002, defendants were not yet in a position to begin validation activities – these activities were not even scheduled until *the end of the third quarter 2002*. Thus, despite assurance of no significant manufacturing process problems in the July 1, 2002 Johnson & Johnson press release, the Wilmington facility was in fact still wholly unable to begin commercial manufacture of the product for the U.S. markets at the expected levels.

106. As a result of defendants' announcement of the non-approvable letter for Risperdal Consta on July 1, 2002, Alkermes' stock price dropped precipitously over the two-day period following the announcement, from a high of \$16.01 to a low of \$4.04, or a drop of 74.8%, on total volume of 29 million shares.

#### **POST CLASS PERIOD REVELATIONS**

##### **A. Failed Merger**

107. On August 14, 2002, Reliant terminated its merger agreement with Alkermes. In a press release entitled "Alkermes and Reliant Pharmaceuticals Mutually Terminate Merger Agreement," Alkermes stated:

The companies agreed to terminate the merger agreement due to general market conditions. There will be no payments triggered by the mutual termination, and each company will bear its own legal and transaction fees.

The termination of the merger agreement does not affect the strategic alliance between the two companies announced in December 2001. Richard Pops, CEO of Alkermes, will continue to serve on the Board of Managers of Reliant.

108. The Reliant merger failed because, although defendants had expected to consummate the transaction based on the overly-inflated value of the Company's stock, they could not control the timing of the FDA's issuance of a rejection letter for Risperdal Consta.

**B. Delayed Approval of Risperdal Consta**

109. Over a year after the Class Period, on October 29, 2003, the FDA finally approved Risperdal Consta for use in treating schizophrenia. The FDA's approval came *a full 26 months* after the NDA was originally submitted and far beyond the original timeline expected by investors and analysts.

**NO STATUTORY SAFE HARBOR**

110. The statutory safe harbor provided for forward-looking statements under certain instances does not apply to any of the allegedly false statements pleaded in this complaint. The specific false statements pleaded herein were not identified as "forward-looking statements" when made. Nor was it stated with respect to any of the statements forming the basis of this complaint that actual results "could differ materially from those projected." To the extent there were any forward-looking statements, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Additionally, to the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made the particular speaker knew that the particular forward-looking statement was false, and/or the forward-looking statement was authorized and/or approved by an executive officer of Alkermes who knew that the statement was false when made.

**APPLICABILITY OF PRESUMPTION OF RELIANCE:  
FRAUD-ON-THE-MARKET DOCTRINE**

111. At all relevant times, the market for Alkermes' stock was an efficient market for the following reasons, among others:

112. Alkermes' stock met the requirements for listing and was listed and actively traded on the NASDAQ, a highly efficient and automated market;

113. As a regulated issuer, Alkermes was required to, and did, file periodic public reports with the SEC and the NASDAQ;

114. Alkermes and the Individual Defendants regularly communicated with public investors via established market communication mechanisms, including through regular dissemination of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services;

115. Alkermes was followed by several securities analysts employed by major brokerage firms who wrote reports which were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace; and

116. As a result of the foregoing, the market for Alkermes' stock promptly digested current information regarding Alkermes from all publicly available sources and reflected such information in Alkermes' stock price. Under these circumstances, all purchasers of or those who otherwise acquired Alkermes' securities during the Class Period suffered similar injuries as a result of the artificial inflation in Alkermes' securities and a presumption of reliance applies.

**FIRST CLAIM FOR RELIEF**  
**For Violation of §10(b) of the Exchange Act and Rule 10b-5**  
**Against All Defendants**

117. Plaintiff incorporates ¶¶1-116 by reference.

118. During the Class Period, defendants disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading.

119. Defendants violated §10(b) of the Exchange Act and Rule 10b-5 in that they:

- (a) Employed devices, schemes and artifices to defraud;
- (b) Made untrue statements of material facts or omitted to state material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading; or
- (c) Engaged in acts, practices, and a course of business that operated as a fraud or deceit upon plaintiff and others similarly situated in connection with their purchases of Alkermes common stock during the Class Period.

120. Plaintiff and the class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Alkermes common stock. Plaintiff and the class would not have purchased Alkermes common stock at the price they paid, or at all, if they had been aware that the market price had been artificially and falsely inflated by defendants' misleading statements.

121. As a direct and proximate result of these defendants' wrongful conduct, plaintiff and the other members of the class suffered damages in connection with their purchases of Alkermes common stock during the Class Period.

**SECOND CLAIM FOR RELIEF**  
**For Violation of §20(a) of the Exchange Act**  
**Against All Defendants**

122. Plaintiff incorporates ¶¶1-121 by reference.

123. The Individual Defendants acted as controlling persons of Alkermes within the meaning of §20(a) of the Exchange Act. By reason of their positions as officers and/or directors of Alkermes, and their ownership of Alkermes stock, the Individual Defendants had the power and authority to cause Alkermes to engage in the wrongful conduct complained of herein. Alkermes controlled each of the Individual Defendants and all of its employees. By reason of such conduct, the Individual Defendants and Alkermes are liable pursuant to §20(a) of the Exchange Act.

**CLASS ACTION ALLEGATIONS**

124. Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons who purchased Alkermes common stock (the “class”) on the open market during the Class Period. Excluded from the class are defendants.

125. The members of the class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court. During the Class Period, Alkermes had more than 54 million shares of outstanding stock, owned by hundreds if not thousands of persons.

126. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the class which predominate over questions which may affect individual class members include:

- (a) Whether the Exchange Act was violated by defendants;
- (b) Whether defendants omitted and/or misrepresented material facts;
- (c) Whether defendants’ statements omitted material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading;

(d) Whether defendants knew or deliberately disregarded that their statements were false and misleading;

(e) Whether the price of Alkermes common stock was artificially inflated; and

(f) The extent of damage sustained by class members and the appropriate measure of damages.

127. Plaintiff's claims are typical of those of the class because plaintiff and the class sustained damages from defendants' wrongful conduct.

128. Plaintiff will adequately protect the interests of the class and has retained counsel who are experienced in class action securities litigation. Plaintiff has no interests which conflict with those of the class.

129. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

#### **PRAYER FOR RELIEF**

WHEREFORE, plaintiff prays for judgment as follows:

- A. Declaring this action to be a proper class action pursuant to Fed. R. Civ. P. 23;
- B. Awarding plaintiff and the members of the class damages, interest and costs; and
- C. Awarding such equitable/injunctive or other relief as the Court may deem just and proper.

**JURY DEMAND**

Plaintiff demands a trial by jury.

DATED: July 12, 2004

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**CERTIFICATE OF SERVICE**

I, Shana E. Scarlett, of the law firm of Lerach Coughlin Stoia & Robbins LLP, hereby certify that a true copy of the above document was served upon the attorney of record for each party by mailing a copy of same, postage prepaid, on July 12, 2004.

/s/ Shana E. Scarlett  
Shana E. Scarlett